REV. 1/89

COMMONWEALTH OF VIRGINIA
Department of Health Professions
1601 Rolling Hills Drive
Richmond, Virginia 23229

DATE:_____
TIME:_____
MILEAGE:_____
INSPECTION HOURS:_____

Manufacturer's Inspection Report

Facility Name:_____ Permit No._____ Exp. Date_____

Address:_____

Owner:_____

Supervising Pharm.:_____ Lic. No._____ Exp. Date_____

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FACILITY:	YES	NO	DOCUMENTATION
1. Required licenses properly displayed?	____	____	
SAFEGUARDS AGAINST DIVERSION OF DRUGS:			
2. Sound, microwave, photoelectric, ultrasonic, or other generally accepted device installed in each drug storage and manufacturing area?	____	____	
a. Device maintained in operating order?	____	____	
b. Device protects immediate drug storage and manufacturing area.	____	____	
c. Device have auxiliary power source?	____	____	
d. Storage area for Schedule II through V drugs restricted to a limited number of designated employees?	____	____	
e. Reasonable measures taken to prevent pilfering of drugs from restricted area?	____	____	
DRUG INVENTORY AND RECORDS:			
3. Schedule II through V drug records maintained at facility for two years?	____	____	
4. Required inventories of Schedule II through V drugs:			
a. Biennial inventory?	____	____	
(1) Inventory date:_____			
(2) Opening of business:_____			
(3) Close of business:_____			
(4) Inventory Signed _____ (name)			
5. Inventories and records of Schedule II drugs maintained separately from all other records?	____	____	
6. Inventories and records of Schedule III through V drugs maintained separately or with records of Schedule VI drugs?	____	____	
7. Schedule II through V records maintained at same location as stock of drug to which records pertain?	____	____	
8. Receipt of Schedule II through V drugs dated with the actual date of receipt?	____	____	
9. Schedule II distribution records maintained separately from other distribution records?	____	____	

WHITE (ORIGINAL)-TO INSPECTION UNIT YELLOW-TO PERMIT HOLDER GREEN-TO INSPECTION UNIT PINK-INSPECTOR

	YES	NO	DOCUMENTATION
Drug Inventory and Records (cont.):			
10. Schedule III through V distribution records maintained separately or filed with Schedule VI distribution records.	____	____	
11. Distribution records include:			
a. Date distributed?	____	____	
b. Name and address of person receiving drug?	____	____	
c. Name and strength of drug?	____	____	
d. Quantity distributed?	____	____	
e. Lot or control number?	____	____	
f. Description of Dosage Form	____	____	
BUILDING AND FACILITIES:			
12. Building contain defined areas to prevent mix-ups?	____	____	
13. Defined areas include:			
a. Quarantine area?	____	____	
b. Storage area for rejected components?	____	____	
c. Storage area for released components?	____	____	
d. Packaging and labeling area?	____	____	
e. Control and laboratory area?	____	____	
f. Separate area for processing penicillin products?	____	____	
14. Facility maintained temperature maintained between 59–86°F? (Temperature _____)	____	____	
15. Washing and toilet facilities include:			
a. Hot and cold running water?	____	____	
b. Soap or detergent?	____	____	
c. Air devices or single-service towels?	____	____	
d. Toilet?	____	____	
SANITATION:			
16. Facility clean and sanitary?	____	____	
17. Written procedure for cleaning schedule?	____	____	
18. Written procedure for use of insecticides and sanitizing agents?	____	____	
EQUIPMENT:			
19. Equipment clean?	____	____	
20. Written procedure for maintaining and cleaning equipment?	____	____	
21. Records maintained on cleaning and sanitizing equipment?	____	____	

	YES	NO	DOCUMENTATION
CONTROL OF COMPONENTS, DRUG PRODUCTS, CONTAINER AND CLOSURES:			
22. Written procedures describing receiving, identifying, storing, handling, sampling, and testing components?	____	____	
23. Components, drug containers, and closures stored under quarantine until tested and released?	____	____	
24. Records maintained of testing components prior to use?	____	____	
25. Rejected components identified and controlled under a quarantine system?	____	____	
PRODUCTION AND PROCESSING CONTROLS:			
26. Written procedures to assure drug products' identity, strength, quality, and purity?	____	____	
27. Procedures include:			
a. Charge-in components?	____	____	
b. Calculations of yield?	____	____	
c. Equipment identification?	____	____	
d. Sampling and testing in-process materials and drug products?	____	____	
e. Time limitations on productions?	____	____	
f. Control of contamination?	____	____	
g. Reprocessing and batching?	____	____	
PACKAGING AND LABELING CONTROL:			
28. Written procedures describing receiving, identifying, storing, handling, sampling, testing, and approving labels?	____	____	
39. Procedures utilized to reconcile quantities of labels issued and used?	____	____	
30. Excess labels bearing lot number destroyed?	____	____	
31. Written procedures describing controls for issuing labels?	____	____	
32. Written procedures to assure correct labels, labeling, and packaging are used?	____	____	
33. Packaging and labeling products examined during finishing operations?	____	____	
34. Samples collected at completion of finishing operation and visually examined?	____	____	
35. Results of examination recorded?	____	____	

	YES	NO	DOCUMENTATION
LABORATORY CONTROLS:			
36. Written procedures for sampling and testing?	____	____	
37. Procedures include:			
a. Determination for conformance for identity and strength of each active product?	____	____	
b. Testing, as necesary, of each batch for microorganisms?	____	____	
38. Written testing program to assess the stability of drug products?	____	____	
39. Representative reserve sample of each lot or batch of drug retained?	____	____	
40. Sample retained for one year after expiration date of last lot or batch?	____	____	
41. Sample retained in same container in which product is marketed?	____	____	
RECORDS AND REPORTS:			
42. Record maintained for equipment cleaning and use?	____	____	
43. Master production and control records maintained for each batch of drug product?	____	____	
a. Reproduction of master production or control record checked, dated, and signed?	____	____	
b. Documentation that each step in the process was accomplished?	____	____	
c. Records reviewed by quality control unit to determine compliance with written procedures?	____	____	
44. Laboratory records maintained on all tests to assure compliance with all written procedures?	____	____	
45. Complaint files maintained, which includes:			
a. Written procedures for handling written and oral complaints?	____	____	
b. Written record maintained in a file designated for drug product complaints?	____	____	
c. Record maintained for one year after expiration date of product or after the date the complaint was received?	____	____	

GENERAL REMARKS:

General Remarks (Continued):

ACTION TAKEN:

(1) _____ New Inspection
(2) _____ Routine Inspection
(3) _____ Reinspection
(4) _____ Drug Destruction
(5) _____ Drug Audit
(6) _____ Other _____ (Specify)

ACKNOWLEDGEMENT:

This manufacturer has been inspected by an inspector of the Department of Health Professions. The results of the inspection have been noted. I acknowledge that the noted conditions that have been deemed by the inspector as not being in compliance have been explained to me and that I have received a copy of this inspection report.

_____ Inspector (Dept. of Health Professions)

_____ Person in Charge

_____ Date

_____ Time of Exit

_____ Title of Authorized Individual

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FOR OFFICE USE ONLY

Violations this inspection: _____

Violations Previous Inspecation: _____

Repeated Violations: _____

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